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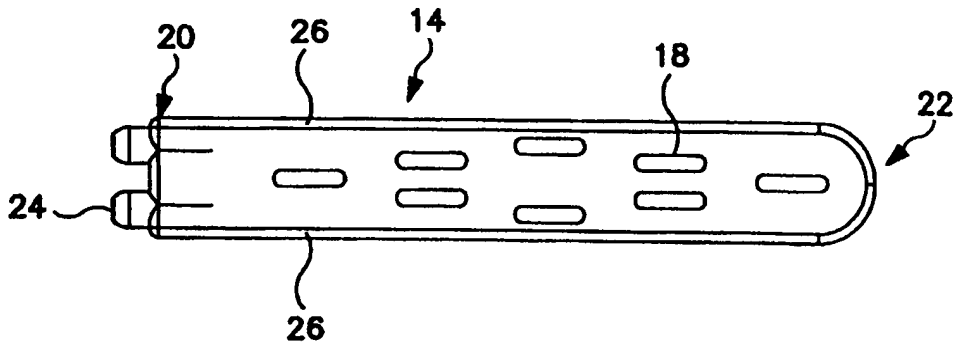

(57) Abstract

An implantable medical lead for spinal cord stimulation includes a lead paddle having an array of multiple overlapping electrode contacts each coupled to a wire conductor of a lead body. The wire conductor in turn may be coupled to an implantable pulse generator or other stimulation device. The lead paddle with an array of overlapping electrode contacts provides more complete electrical stimulation coverage to targeted human tissue because there is no potential for a targeted fiber to pass through the overlapping array of electrode contacts without having some potential for correct electrical stimulation by a contact.

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MULTIPLE ELECTRODE LEAD BODY FOR SPINAL CORD STIMULATION

Field of the Invention

The present invention relates generally to implantable medical stimulators and more particularly to medical leads having a plurality of electrode contacts.

Description of the Related Art

Electrical stimulation of electrically excitable tissue such as the brain and/or nerve tissue of the spinal cord or peripheral nerve can result in pain reduction and/or elimination for the living organism having the stimulated electrically excitable tissue. Thus, for example, medical leads having electrode contacts have been implanted near the spinal column of the human body to provide pain relief for chronic intractable pain. The nerve tissue within the spinal column is stimulated electrically to reduce pain sensations at other parts of the body.

Depending on the location of the pain sensation, and the particularities of each different human body, the parameters of the stimulation signals applied near the electrically excitable tissue are adjusted to optimize pain reduction and/or elimination. For example, the area of excitation within the spinal column and the intensity of excitation can be varied by corresponding adjustment of the parameters of the stimulation signals.

In order to vary the area of excitation, an array of electrodes may be implanted near the nerve tissue within the spinal column or peripheral nerve. Then, each of those electrodes can be configured to have a respective one of a positive, negative, or neutral polarity such that the desired area of the nerve tissue within the spinal column is

electrically stimulated. In addition, parameters of the respective stimulation signal applied on each of those implanted electrodes can be varied for a corresponding variation in area of excitation within the spinal column and in the intensity of excitation at the pain site. Once the array of electrodes is implanted, a clinician who is knowledgeable of the effects of electrical stimulation may vary the parameters of the respective stimulation signal applied on each of the implanted electrodes. The patient may rate the effectiveness in pain reduction for each variation in the parameters of the stimulation signals. If electrical stimulation of nerve tissue does result in sufficient pain reduction for the patient, then the medical lead is implanted for the long term with stimulation signals having parameters that lead to optimized pain reduction for the particular patient.

However, prior art electrode arrays do not provide adequate stimulation coverage. In some spinal cord stimulation cases, the best stimulation points, for example, nerve fibers, are sufficiently far apart that the side-to-side spacing between electrodes on current leads is not adequate to span them. In addition, the electrode arrays have electrode contacts that are spaced axially and longitudinally along a lead body such that gaps remain between adjacent contacts. As a result of these gaps, nerve fibers may pass between the electrode contacts and be unavailable for stimulation. This is highly undesirable when a clinician is trying to cover an entire targeted area because the clinician does not necessarily know where the desired fibers are within this targeted area of excitation.

SUMMARY OF THE INVENTION

The present invention recognizes and provides a solution to the problems of inadequate electrode array coverage in providing a unique lead paddle that has an array of spaced apart, but yet overlapping, electrode contacts for complete nerve fiber stimulation of a targeted area.

Accordingly, an object of the present invention is to provide for a unique implantable medical lead having a lead paddle which includes a plurality of electrode contacts, such as an array, for transmitting stimulation signals to surrounding human tissue. Another object of the invention is to provide a lead paddle that has an array of overlapping electrode contacts for more complete stimulation coverage of a targeted area of excitation. Further, another object of the invention is to provide a lead paddle that has an array of overlapping electrode contacts that span distant nerve fibers and at the same time provide combinations that cover nerve fibers that may be close together. Yet another object of the invention is to provide a lead paddle that has an array of overlapping electrode contacts wherein the parameters of the stimulation signals applied to each electrode can be controlled to stimulate targeted fibers. Still another object of the invention is to provide a multiple electrode lead paddle that is curved laterally to approximately match the curve of the outside of the dura mater which encircles the spinal cord.

The present invention provides an implantable medical lead, for spinal cord stimulation, comprising a lead paddle having an array of about eight axially and laterally spaced electrode contacts that overlap laterally. Thus, the array of overlapping electrode

contacts provides for more complete coverage of targeted stimulation areas because the overlapping electrode contacts prevent nerve fibers from passing through the array without having some potential for correct electrical stimulation by an electrode contact.

The disclosed distribution of electrode contacts on a curved lead paddle also provides horizontal stimulation near the entry zone where the nerve enters the spinal cord. This new arrangement of electrode contacts is based on a more current understanding of the pathological processes that are occuring horizontally in the spinal cord rather than just the previously understood vertical pathological changes going toward the brain. In order to stimulate near the entry zone where the nerve enters the spinal cord, the curved paddle with a lateral most contact point will allow lateral stimulation while the other electrode contact points on the curved paddle will allow stimulation across the spinal cord for pain relief. Additionally, the curved paddle allows for a more close proximity of the stimulating electrode to the spinal cord which reduces the voltage requirements because of the shorter distance between the stimulating electrode contact and the spinal cord. Moreover, the curved lead paddle ensures that horizontal migration of the lead paddle will not take place, unlike the conventional percutaneously placed electrodes.

The full range of objects, aspects and advantages of the invention are only appreciated by a full reading of this specification and a full understanding of the invention. Therefore, to complete this specification, a detailed description of the invention and the preferred embodiment follows, after a brief description of the drawing.

BRIEF DESCRIPTION OF THE DRAWING

The preferred embodiment of the invention will be described in relation to the accompanying drawing. In that drawing, the following figures have the following general nature:

Fig. 1 is a plan view of a medical lead having a lead paddle of the present invention coupled to lead bodies.

Fig. 2 is a plan view of the lead paddle having the preferred array of electrode contacts of the present invention.

In the accompanying drawing, like reference numbers are used throughout the various figures for identical structures.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Fig.1, a preferred embodiment of the invented medical lead 10 for spinal cord, peripheral nerve and deep brain stem stimulation comprises at least one lead body 12 and a preferred lead paddle 14. The lead paddle 14 has an array of electrode contacts 18 and is coupled at one end to the lead body. The lead body 12 further comprises at least one wire conductor. The number of wire conductors may be increased to two, three, or more, dependent on need and significant generally to the number of electrical signals to be generated.

Each proximal end 16 of a lead body such as the illustrated lead bodies 12 may be coupled to an implantable neurological pulse generator, additional, intermediate wiring, or other stimulation device. An example of such a neurological pulse generator is the ITREL II system from Medtronic, Inc., Minneapolis, Minnesota. The stimulation pulses produced by the implantable neurological pulse generator are carried from the pulse generator through the proximal ends 16 of the lead bodies 12, via the wire conductor, to distal ends of the lead bodies 12, and thereby to a coupled lead paddle 14 having at least one electrode contact 18.

One or more of the electrode contacts 18 on the lead paddle 14 transmit the stimulation pulses to targeted human tissue. As preferred, the illustrated structure transmits stimulation pulses from a pair of the contacts 18. The pair is selected through testing of the efficacy of alternate electrode pairs. Alternatively, the illustrated structure may transmit stimulation pulses from one electrode contact 18 or a plurality of electrode contacts 18 depending on the desired stimulation.

Though the preferred embodiment employs fully implantable elements, systems employing partially implanted generators and R-F coupling may also be used in the practice of the present invention. Such systems are also available from Medtronic, Inc., under the trademarks X-trel and Mattrix.

Each lead body 12 is generally a straight wire metal conductor within an insulating sheath. The insulating sheath is formed of an inert material such as polyurethane. Varieties of lead bodies are contemplated. Explanation of the reasoning for specific lead bodies is beyond this invention.

The lead paddle 14 of the preferred embodiment has a plurality of electrode contacts 18 arrayed along the length and across the width of the lead paddle 14. Varieties of alternate arrays and numbers of electrodes are contemplated. The lead paddle 14 with the array of electrode contacts 18 transmit stimulation signals to surrounding human tissue. The implantable pulse generator provides respective stimulation signals having specified signal parameters to selected contacts 18 in the array. Thus, depending on the desired location and amount of tissue stimulation, the parameters of the stimulation signals can be controlled and directed to selected electrode contacts for targeted stimulation. For spinal cord stimulation, the lead paddle 14 is placed outside the dura mater and stimulation occurs through the dura mater to the targeted tissue fibers. The lead paddle 14 is properly positioned, as known as a result of fluoroscopy and trial stimulation of tissue fibers.

Referring to Fig. 2, as most preferred, the lead paddle 14 has an array of eight electrode contacts 18 spaced axially along the length of the lead paddle and laterally

across the width. This array of overlapping electrode contacts 18 spans distant stimulation points, for example, nerve fibers, and at the same time provides combinations that cover stimulation points that may be close together. A clinician can thus direct stimulation to various combinations of stimulation points covered by the array of the present invention by controlling the amount and frequency to each electrode contact 18. Experience shows that beneficial stimulation occurs when the electrode contacts 18 are within 3 millimeters from the midline of the lead paddle 14. Thus, total lateral spacing of the electrode contacts 18 along the width of lead paddle 14 is preferably 6 millimeters. Consequently, the width of the lead paddle 14 is approximately 6 millimeters. Variations of the spacing of the electrode contacts 18 and the width of the lead paddle 14 can be made and are contemplated. The axial length of the lead paddle 14 may be any suitable length to fit the desired number of electrode contacts 18 onto a lead paddle 14. The thickness of the lead paddle is sufficient to fit an electrode contact and accompanying wire conductor. It is preferred that the lead paddle 14 be as thin as possible to reduce the possibility of compression of the spinal cord.

In a preferred embodiment, and based on past studies to avoid lesions from smaller contact areas, the size of the electrode contacts 18 are approximately 12 square millimeters. However, electrode contacts of other suitable sizes are contemplated and within the scope of this invention. Thus, the lead paddle 14 has the shape of a slender elongated paddle.

The lead paddle 14 may be made of any suitable material, such as silicone rubber, adapted to be disposed within the human body. The lead paddle has a proximal

end 20 and a distal end 22. The proximal end 20 provides at least one opening 24 for the wire conductors to pass into the lead paddle and couple to the electrode contacts 18. The distal end 22 is rounded and curved to prevent abrasion of human tissue for safer placement of the lead paddle at the desired stimulation area. The sides 26 of the lead paddle 14 are also rounded to prevent abrasion of tissue during implantation and while implanted. The lead paddle 14 may also be curved laterally to match the curvature of the dura mater, which encircles the spinal cord. A curved lead paddle 14 enhances the likelihood of fiber stimulation by allowing the electrode contacts 18 to be in close proximity to the targeted tissue fibers thus improving fiber recruitment. Moreover, a curved lead paddle 14 reduces the potential for compression of the spinal cord.

As most preferred, the electrode contacts 18 in the lateral direction overlap. The outer edges of an electrode contact 18 will overlap the outer edges of an adjacent electrical contact 18 in the lateral direction. That is, there are no gaps between electrode contacts 18 along the width of the lead paddle 14. Therefore, there is no potential for targeted ascending and descending nerve fibers to pass through the array of electrode contacts 18 without having some potential for correct electrical stimulation by a contact. Moreover, the laterally most spaced electrode contacts 18

In a preferred embodiment of an array of eight electrode contacts, the array defines a diamond configuration. The diamond configuration allows for lateral overlapping of electrode contacts 18 and adequate axial spacing.

The preferred embodiments of the invention are now described as to enable a person of ordinary skill in the art to make and use the same. Variations of the preferred

embodiment are possible without being outside the scope of the present invention. Therefore, to particularly point out and distinctly claim the subject matter regarded as the invention, the following claims conclude the specification.

What is claimed is:

1. An implantable medical lead having at least one lead body, for electrical stimulation, comprising:

a lead paddle having an array of axially and laterally spaced electrode contacts, whereby the array of axially and laterally spaced electrode contacts provides for coverage of targeted stimulation areas.

2. An implantable medical lead as in claim 1, wherein the array of axially and laterally spaced electrode contacts overlap laterally on the lead paddle.

3. An implantable medical lead as in claim 1, wherein the array comprises eight or more electrode contacts.

4. An implantable medical lead as in claim 1, wherein the lead paddle is curved laterally to match the shape of a human dura mater.

5. An implantable medical lead as in claim 1, wherein the array of electrode contacts is in a diamond configuration.

6. An implantable medical lead as in claim 1, wherein the lead paddle comprises silicone rubber.

7. An implantable medical lead having at least one lead body, for electrical stimulation, comprising:

a lead paddle having an array of multiple axially and laterally spaced electrode contacts, the electrode contacts overlapping laterally,

whereby the array of axially and laterally spaced electrode contacts provides for coverage of targeted stimulation areas.

8. An implantable medical lead as in claim 7, wherein the lead paddle is curved laterally to match the shape of a human dura mater.

9. An implantable medical lead as in claim 7, wherein the array of axially and laterally spaced electrode contacts is in a diamond configuration.

10. An implantable medical lead having at least one lead body, for electrical stimulation, comprising:

a silicone rubber lead paddle having an array of eight axially and laterally spaced electrode contacts, the electrode contacts overlapping laterally, the lead paddle curved laterally to match the curvature of a human dura mater,

whereby the array of axially and laterally spaced electrode contacts and the curved lead paddle provide for coverage of targeted stimulation areas.

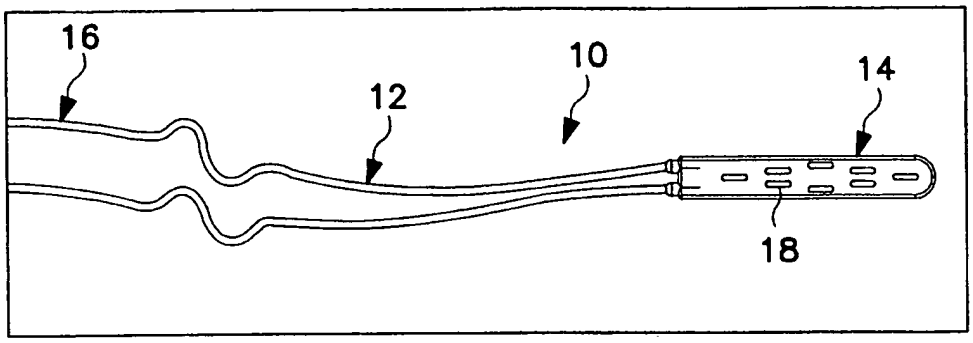

FIG. 1

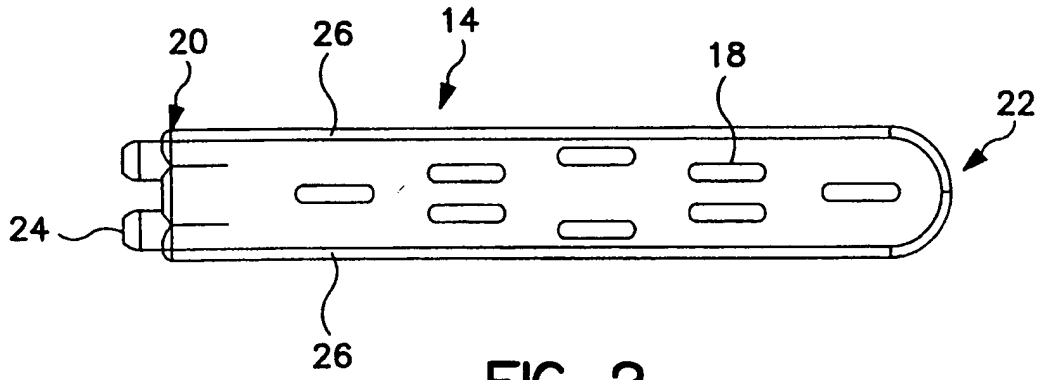

FIG. 2

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 99/07941

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/05

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 724 467 A (AVERY R ET AL) 3 April 1973	1,6
A	see column 2, line 38-54; figures 4,5	2,3,5,7, 9,10
X	US 5 643 330 A (HOLSHEIMER JAN ET AL) 1 July 1997	1,3
A	see claims 13,20; figure 20	4,7,8,10
X	DE 195 25 570 A (FRAUNHOFER-GESELLSCHAFT ZUR FÖRDERUNG DER ANGEWANDTEN FORSCHUNG E.V.) 18 January 1996	1,3,6
A	see column 4, line 21-45	7,10
A	US 5 733 322 A (STARKEBAUM WARREN L) 31 March 1998 see column 3, line 60-61	1,3,7,10

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
1 July 1999	09/07/1999

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Information on patent family members

Inter nal Application No
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